REMARKS

The Amendment, filed in response to the Office Action mailed March 19, 2010, is believed to fully address all and every issue raised in the Office Action. Favorable reconsideration and allowance of the application are respectfully requested.

Disposition of Claims

Claims 1-11 have been pending in the application. Claims 1-11 have been considered and rejected in the Office Action.

In the instant Amendment, claims 1 and 6 are amended to further clearly set forth the claimed subject matter by incorporating the feature of original claim 3. Claim 3 is canceled, accordingly.

Upon entry of the Amendment, claims 1, 2 and 4-11 will be all the claims pending in the application.

No new matter is introduced. Entry and consideration of the amendment are respectfully requested.

Response to Claim Rejection - 35 USC § 103

In the Office Action, claims 1-11 are rejected under 35 U.S.C. 103(a) as assertedly being unpatentable over Compton et al (US Pregrant Pub 2003/0059471; "Compton").

Compton is cited as teaching making flakes which contain drugs (abstract), in which the flakes are made from polymers which include hydroxypropylmethylcellulose and poly(vinyl acetate) and the drugs may include tamsulosin hydrochloride.

While acknowledging that Compton fails to teach all and every element of the claims (and thus not anticipate the claimed subject matter), the Examiner asserts that it would have obvious to have selected hydroxypropylmethylcellulose and poly(vinyl acetate) from the list of potential polymers and the optional enteric coating from within a prior art disclosure, to arrive compositions "yielding no more than one would expect from such an arrangement."

Applicant respectfully traverses.

Currently presented claim 1 is directed to a composition for oral administration comprising tamsulosin hydrochloride, polyvinylacetate, and a water-soluble hydroxypropylmethylcellulose, wherein the amount of polyvinylacetate ranges from 20 parts by weight to less than 1000 parts by weight based on 1 part by weight of tamsulosin hydrochloride.

Meanwhile, Compton discloses drug-containing flakes which are adaptable to patient populations that have trouble chewing and swallowing. In this regard, Compton teaches that the flakes can be made of any one of a variety of materials, polymers or non-polymers, while enumerating almost all types of polymers and drugs.

In other words, Compton aims to provide flakes for eliminating or reducing the gritty feel characteristic of particles to enhance mouth feel, and it provides a general composition which can be applied for any type of active substances rather than a specific drug like tamsulosin hydrochloride. Although Compton mentions tamsulosin hydrochloride in the long boilerplate list of drugs (i.e., pharmaceutical active substances), they neither provide guidance for a specific combination of tamsulosin hydrochloride, polyvinylacetate and hydroxypropylmethylcellulose, nor disclose a composition comprising tamsulosin hydrochloride in the working examples.

In contrast, for the purpose of improving controlled tamsulosin hydrochloride release characteristics over a long period of time, the present invention provides a composition having tamsulosin hydrochloride and polyvinylacetate in a weight ratio between 20 parts and less than 1000 parts.

Accordingly, the objects of the present invention and Compton completely different from each other; and there is **no motivation for a person skilled in the art who tries to control tamsulosin hydrochloride release characteristics to combine the three (3) components**, i.e., tamsulosin hydrochloride, polyvinylacetate, and hydroxypropylmethylcellulose. Thus, the constitution of the inventive composition cannot be easily derived from Compton.

Moreover, the **currently claimed composition exhibits a markedly improved controlled tamsulosin hydrochloride release characteristics over a long period** of time without an initial burst release. To further demonstrate the remarkable effects of the present invention, one of the inventors submits a Declaration in accordance with 37 C.F.R. section 1.132 together with this response.

Submission of Declaration Under 37 C.F.R. §1.132

As can be seen from the concurrently Declaration, executed by Jong Soo WOO, it is clear that the compositions which do not satisfy each and every requirements of the present invention, fail to exhibit the desired release rate of tamsulosin hydrochloride, and thus, the specific tamsulosin hydrochloride to polyvinylacetate weight ratio as claimed is one of the essential technical features of the present invention.

In the Declaration, Mr. Woo concludes, from the data obtained from additional experiments and data disclosed in the specification, that the formulations having a composition outside the claimed range fail to show the desired tamsulosin hydrochloride release properties. That is, the formulation of Comparative example 2 having a weight ratio of 1:10 (tamsulosin hydrochloride : polyvinylacetate), which is outside the claimed range, exhibited an initial burst release of tamsulosin hydrochloride, and the formulation of Comparative Example 1 having a weight ratio of 1:20, which falls within the claimed range, exhibited a sustained release profile.

Also, in the case of the formulation of Comparative Example 3, which has a weight ratio of 1:1000, which is outside the claimed range, shows undesirably slowed or delayed release of tamsulosin hydrochloride, thereby failing exhibiting sufficient pharmacological effects.

Accordingly, Applicant respectfully submits that currently presented claims 1, 2, and 4-11 are patentable over Compton. Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number **202-775-7588**.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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